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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,572	11/15/2000	Kenneth A Giuliano	97.022-K2	5670
20306	7590	09/27/2004	EXAMINER	
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP 300 S. WACKER DRIVE 32ND FLOOR CHICAGO, IL 60606			WALICKA, MALGORZATA A	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/713,572	<b>Applicant(s)</b> GIULIANO ET AL.	
	<b>Examiner</b> Malgorzata A. Walicka	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 10-17 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 10-17 and 24-31 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Inventions of Group I. Claim 10, 13, 14, 15, 16, 17 in part, drawn to a 3-domain biosensor comprising detectable polypeptide signal, protease recognition site and reactant target sequence of any of SEQ ID NO: 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 150, and 152, classified in class 530, subclass 387.3.
- Inventions of Group II. Claim 11, 24, 26, 28, 30, 17 in part, drawn to a four-domain biosensor comprising detectable polypeptide signal, protease recognition site, reactant target sequence of any of SEQ ID NO: 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 150, and 152 and at least one product target sequence wherein the reactant target sequence and product target sequence are separated by protease recognition site, classified in class 530, subclass 387.3.
- Inventions of Group III. Claim 12, 25, 27, 29, and 31, 17 in part, drawn to a five-domain biosensor comprising detectable polypeptide signal, protease recognition site, reactant target sequence of any of SEQ ID NO: 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148,

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150, and 152, at least one product target sequence and at least one detectable polypeptides signal, wherein the first detectable polypeptide is separated from the fifth domain, i.e. the second detectable polypeptide signal, by a protease recognition site; classified in class 530, subclass 387.3.

Inventions of Groups I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of Groups I-III are different chemical compounds, consisting of 3, 4 or 5 domains that have different structure, although every of these chemicals is a protease biosensor.

Because these inventions are distinct for the reasons given above and required separate searches in sequence databases as well as patent and non-patent literature, restriction for examination purposes as indicated is proper.

Furthermore, Groups I-III are three genera of biosensor species whose biochemical functions are different because they sense different biochemical processes in which said proteases are involved as indicted by different reactant target or product target sequences. Each of the species consist of 3, 4, or 5 domains, wherein the domain 1 and 2 is any of SEQ ID NOs:34, 38, 40, 42, 44, 46, 48, 50 and 52; domain 2 or 4 is any of SEQ ID NO:54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84,

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86, 88, 90, 92, 94, 96, 98, 100, 102, 104, 106, 108, 110, 112, 114, 116, 118, 120 and 122, and domain 3 is any of SEQ ID NO: 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 150, and 152.

In addition to election of any of Groups I-III, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, i.e. to elect one combination of the listed sequences, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently all claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35


U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (571) 272-0944. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m. If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (571) 272-0928. The fax phone number for this Group is (571) 273-0937.

Malgorzata A. Walicka, Ph.D.

Patent examiner

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REBECCA E. PROUTY  
PRIMARY EXAMINER  
GROUP 1800  
1600